

Application No. 10/521,295
May 13, 2010

AMENDMENTS TO THE CLAIMS:

Claim 1. (Currently Amended) A method for a physical pre-treatment of an active substance to provide cores, characterized in that it comprises adding a poor solvent or a mixture of solvents to the active substance or to a mixture of the active substance with one or more excipients, the solubility of the substance in said solvent being less than 0.1 g/L, followed by drying to a final humidity of about 2.5%, wherein the active substance comprises micronized clarithromycin, wherein ~~at least about 90% of~~ the micronized clarithromycin particles ~~are~~ have a particle size d(0.9) of about 30 μ m ~~or less~~ in size and enter a direct mixture for tabletting or encapsulating.

Claim 2. (Original) A method for a physical pre-treatment of an active substance according to claim 1, characterized in that said method comprises humidifying with water.

Claim 3. (Previously Presented) A method for a physical pre-treatment of an active substance according to claim 1, wherein the poor solvent is an aqueous solution comprising water and at least one pharmaceutically acceptable excipient selected from the group consisting of binders, buffers, emulgators, and surfactants.

Claim 4. (Original) A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the part of the active substance in the mass of the whole formulation is over about 30%.

Claim 5. (Original) A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the part of the active substance in the mass of the whole formulation is over about 40%.

Claim 6. (Cancelled).

Claim 7. (Original) A method for a physical pre-treatment of an active substance according to claim 6, characterized in that the solvent used is water, wherein the solubility of the active substance is under about 0.1 g/L.

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Claim 8. (Original) A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the active substance, if micronized, is difficult to be directly tabletted or encapsulated.

Claim 9. (Previously Presented) A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the active substance comprises particles thereof which are large, brittle and/or porous.

Claims 10 – 12. (Cancelled)

Claim 13. (Previously Presented) A method for a physical pre-treatment of an active substance according to claim 12, characterized in that the cores are coated.

Claim 14. (Original) A method for a physical pre-treatment of an active substance according to claim 13, characterized in that the coating also contains a polymer having viscosity of up to about 15 mPas.

Claim 15. (Original) A method for a physical pre-treatment of an active substance according to claim 14, characterized in that the coating contains at least about 10% of a polymer having viscosity of up to about 15 mPas.

Claim 16. (Previously Presented) A method for a physical pre-treatment of an active substance according to claim 14, characterized in that the polymer used in the coating has a viscosity of over about 6 mPas.

Claim 17. (Previously Presented) A pharmaceutical formulation, selected from the group consisting of a tablet and a capsule, characterized in that the active substance is modified according to the method of claim 1.

Claim 18. (Currently Amended) A pharmaceutical formulation, selected from the group consisting of a tablet and a capsule, prepared according to the method of claim 1 for use in medicine for the treatment ~~and prevention~~ of diseases.

Claim 19. (Cancelled)

Claim 20 (Currently Amended). A clarithromycin tablet, comprising:
a tablet core comprising micronized clarithromycin, wherein the micronized clarithromycin has been pre-treated by adding a poor solvent to the clarithromycin

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followed by drying the clarithromycin, wherein the solubility of the clarithromycin in said solvent is less than 0.1 g/L; and

a film coating over the tablet core, wherein the film coating is applied as a fluid comprising a first film-forming agent having a viscosity of up to about 6 mPas and at least 10% of a second film-forming agent having a viscosity of over 6 mPas and up to about 15 mPas.